Response to "Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States"[1]
March 2004

Introduction

At the request of the Secretary of Agriculture, an international expert Bovine Spongiform Encephalopathy (BSE) panel was convened to review actions taken by the United States in response to a single finding of BSE. The panel, which was organized as a subcommittee of the Secretary's Foreign Animal and Poultry Disease Advisory Committee, provided its report on February 4, 2004.

While the report includes many valuable findings and recommendations, it also presents several conclusions and recommendations that are based on the premise of a higher incidence of BSE in the United States than is suggested by current studies. The report states:

> *"However, it is probable that other infected animals have been imported from Canada and possibly also from Europe. These animals have not been detected and therefore infective material has likely been rendered, fed to cattle, and amplified within the cattle population…"*
>
> *"Now that it has been established that the BSE agent is circulating in North America…"*
>
> *"However, with the passage of time since the importations and the amplification of the agent within North America …"*

However, analyses (see Risk Analysis for Re-opening the Borders to Canada[2], Harvard risk assessment for BSE[3]) indicate that BSE is likely to be found in the U.S. at very low incidence, if at all. Further, it is extremely unlikely to be amplified in animal feeds while mitigation strategies that are in effect reduce the risk in the human food supply to a nearly negligible level. If such amplification had occurred, it is likely that at least some affected animals in the United States, if they exist, would have clinically observable signs of BSE and would have been reported as sick animals even if the cause of their disorder was unknown at the time.

The subcommittee assumes that the two cases identified from Canada represent BSE as a widespread epidemic rather than a small clustered epidemic. However, there is evidence to indicate that the two North American cases are a clustered epidemic. The epidemiologic investigations suggest that the cattle were possibly linked by a common feed supplier.

Greatly different inferences result from these assumptions; the first implies that the disease is randomly spread through the population versus the second that a very small number of cases that are likely linked by a single exposure. The new surveillance plan, announced by the Department on March 15, 2004, will assist with a determination of true prevalence.

Regardless of the varying interpretations of the risk of BSE in U.S. cattle, the report contained many valid findings and useful suggestions. These are addressed below.

Summary of Key Findings and Responses

The report made several positive findings and commended the U.S. actions since finding this BSE positive cow:

- The subcommittee acknowledged the U.S. government's science-based approach to policy formulation.
- The subcommittee commended the Department on the comprehensive and thorough epidemiological investigation. They recommended that the investigation be concluded. USDA did so on February 9, 2004.
- The subcommittee stated that the tracing and recall of the rendered meat and bone meal (MBM) that may have been contaminated with specified risk materials (SRMs) from the index case was effective and appropriate.
- The subcommittee confirmed the action to prohibit air injection stunning for slaughter animals.
- The subcommittee recognized the food safety merit of prohibiting non-ambulatory cattle from entering the human food supply, while cautioning about the challenges this action presents to our surveillance efforts.
- The subcommittee recommended the adoption of rapid screening tests, which is consistent with the Department's announcement to accept applications for licensure of such tests and the use of such tests in the surveillance program.
- The subcommittee acknowledged the importance of effective animal identification and traceability systems, again consistent with the Secretary's announcement to accelerate the implementation of such a plan within the United States.
- The subcommittee also recognized U.S. containment and proper destruction of specific risk materials to protect human health, animal health, and the environment.

In addition, the subcommittee report makes recommendations regarding a number of topics, including surveillance, SRMs, feed restrictions, traceability, and future guidance and strategy.

Surveillance

The subcommittee report states:

> *"The subcommittee recommends testing of all cattle older than 30 months in the above risk populations and strengthening of the passive surveillance system. This will not only establish the prevalence of BSE but also build confidence both domestically and for trading partners. …"*

The United States has had an active surveillance program for BSE since 1990.

After the single find of BSE in the U.S. and in response to the recommendations from the international committee, the current USDA BSE surveillance plan, announced on March 15, 2004, involves testing as many samples as possible from the high risk cattle population (currently estimated at approximately 446,000) for a period of 12-18 months. Data from the European outbreaks indicate that the great majority of BSE cases are found

in the high risk population. This intensified testing would give the Department a firm basis to make adjustments to the current preventive strategy, and would provide data for future risk analyses. Assuming all the BSE positive cattle are part of the high risk population, if a total of 201,000 samples is collected, this level of sampling would allow us to detect BSE at the rate of 1 positive in 10 million adult cattle at a 95 percent confidence level. If a total of at least 268,500 samples is collected, this level of sampling would allow us to detect BSE at the same rate at a 99 percent confidence level.

Strengthening of the passive surveillance system for BSE through outreach and education is an integral part of the USDA surveillance plan. In this regard, USDA's Animal and Plant Health Inspection Service (APHIS) has developed plans to enhance existing educational materials and processes in conjunction with other Federal and State agencies. These outreach efforts will inform veterinarians, producers and affiliated industries of the USDA surveillance goals and the sometimes subtle clinical signs of BSE, and will encourage reporting of suspect or targeted cattle on farm and elsewhere.

The subcommittee report also states:

> *"However, to support the overall surveillance system and encourage reporting at the farm level testing of a random sample of healthy slaughter cattle over 30 months should be strongly considered."*

Additional benefit would be realized if older animals (i.e. animals born before the implementation of the feed ban in August 1997) are tested. The current USDA plan includes testing 20,000 clinically normal adult cattle at slaughter plants, with an emphasis on the oldest cattle population.

Furthermore, the subcommittee recommended expanding the use of laboratories throughout the country to conduct rapid screening tests as part of the BSE surveillance plan. USDA's current surveillance plan meets the subcommittee recommendation as it involves the use of public laboratories contracted to be part of a network of laboratories using newly licensed rapid tests to screen samples for BSE. The National Veterinary Services Laboratories will continue to be the national reference laboratory. The current surveillance plan also includes extensive outreach and education for producers, veterinary students, and veterinarians, to indicate the sometimes subtle clinical signs of BSE and underscore the need to participate in surveillance activities.

Subsequent to their initial report, the subcommittee reviewed the current USDA BSE surveillance plan and indicated that it is comprehensive and scientifically based, and that it addresses the important issues with regard to BSE surveillance in cattle.

Specified Risk Materials

The subcommittee report recommends:

> *"Specifically, processing of skulls and vertebral columns of cattle over 30 months by mechanically recovered meat (MRM) and advanced meat recovery (AMR) systems should be banned. The complete separation of these tissues may be very difficult to implement, therefore, the banning of all mechanical tissue processing methods should be considered."*

USDA has banned the use of mechanically separated beef for human food. AMR product is prohibited from use has human food if it contains central nervous system tissue. In addition, USDA has banned the use of vertebral columns (except those portions without central nervous system tissue) and skulls from cattle 30 months of age and older. USDA has developed procedures to verify the age requirements of cattle that are slaughtered and ensures that establishments are segregating animals correctly.

Establishments that handle cattle 30 months of age and older and that are producing beef through AMR systems are required to segregate these animals from younger animals in order to ensure that the SRMs are appropriately removed and not used in AMR systems. Furthermore, establishments that process the carcasses or parts of cattle are required to develop, implement and maintain written procedures for the removal, segregation and disposition of SRMs, including noncomplying product from beef AMR systems. USDA carries out regulatory verification programs, including the testing of AMR product for central nervous system-type tissue (i.e., spinal cord and DRG) to verify the adequacy of industry systems, as well as to ensure that SRMs are not used in AMR systems. With these measures in place, a total ban on beef produced through AMR systems is not necessary.

Further, the report states:

> *"Unless aggressive surveillance proves the BSE risk in the USA to be minimal according to OIE standards, the subcommittee recommends that the SRM identified below be excluded from both the human food and animal feed chains.*
>
> - *Brain and spinal cord of all cattle over 12 months of age*
> - *Skull and vertebral column of cattle over 12 months of age – these are not inherently infected, but cannot be separated from dorsal root/trigeminal ganglia or from residual contamination with CNS tissue*
> - *Intestine – from pylorus to anus – from all cattle."*

The subcommittee report goes on to say that the proposed U.S. ban on SRMs from cattle over 30 months of age meets Office International des Epizooties (OIE) standards and is a reasonable response pending additional surveillance to more definitively establish minimal risk.

As the Secretary of Agriculture announced on December 30, 2003, SRMs (including the brain, skull, eyes, trigeminal ganglia, spinal cord, dorsal root ganglia, and the vertebral column – excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) are now being removed from all animals over 30 months of age and tonsils and small intestines are removed from cattle of all ages. FSIS is further evaluating whether the dorsal root ganglia and trigeminal ganglia can be removed from the bone in a manner that does not cause contamination. At this time, methods do not appear to exist, or be in common use, that can reliably separate trigeminal ganglia from the skull or dorsal root ganglia from the vertebral column. Meanwhile, the bones housing these materials are considered SRMs because the potentially infective material may not be effectively removed.

As to the recommendation for removal of SRMs from animals over 12 months of age rather than 30 months, we will re-evaluate based on surveillance sampling results. In the

meantime, the subcommittee recognized that removal of SRMs from cattle over 30 months of age is a reasonable compromise.

Regarding the recommendation to remove the entire intestine, scientific evidence does not support the need to remove the entire intestinal tract. Therefore, USDA will require the removal of the small intestine as an appropriate measure to ensure the absence of potentially infective material in human food.

Feed Restrictions

The subcommittee report states:

> *"…the subcommittee believes the partial (ruminant to ruminant) feed ban that is currently in place is insufficient to prevent exposure of cattle to the BSE agent. The current ban reflects the situation in Europe early in the outbreak where, with the benefit of hindsight, it can be concluded that propagation of BSE infectivity continued …"*

Regulation of animal feed is under the jurisdiction of the Food and Drug Administration (FDA). The Harvard Risk Assessment indicated that "Measures in the U.S. that are most effective at reducing the spread of BSE include … the feed ban instituted by the Food and Drug Administration (FDA) in 1997 to prevent recycling of potentially infectious cattle tissues. This feed ban greatly reduces the chance that BSE will spread from an infected animal back to other cattle through feed. Our model reflects incomplete compliance with the FDA feed ban … ."[3]

It should be noted that the 1997 feed ban in the United States was not implemented in response to a situation similar to that which existed in Europe early in the outbreak. In Europe, there were hundreds of thousands of cattle affected with significantly higher risk of feed contamination. The major source of infection in the European epidemic was ruminant-origin MBM, not cross contamination. It is difficult to estimate the number of cases that arose from contamination of ruminant feed from non-ruminant feeds, but it is undoubtedly small compared to ruminant-origin MBM. General awareness as well as current feed manufacturing regulations directly address the risk of cross-contamination in the United States. Thus, the situation is far different than in Europe 10 years ago.

FDA has announced its intent to publish an interim final rule that makes some changes to the current feed ban. They intend to eliminate the exemptions that allow the use of blood products and plate waste in ruminant feed. In addition, they plan to prohibit the use of poultry litter in ruminant feed and to require the use of dedicated facilities in handling prohibited products.

Traceability

The subcommittee report "encourages the implementation of a national identification system that is appropriate to North American farming." This recommendation is well-founded and an essential tool in facilitating control and eradication of animal disease, and in preventing its dissemination.

Design and implementation of a national identification system is well underway. USDA plans to move forward with implementation of a national animal identification system this year, first on a voluntary basis designed to integrate the various types of animal identification programs which currently exist in the U.S. and then scale these programs up to the national level, including those producers and animals that are not currently included in a program. The goal is to create an effective, uniform, consistent and efficient national system.

Several key objectives for such a system have been defined. These include (1) ensuring sufficient flexibility to use current systems or adopt new ones; (2) adopting a technology neutral approach to ensure that all effective technologies can be used; (3) setting clear and objective data standards; (4) facilitating integration with other production management systems that respond to market incentives; and (5) seeking all possible economic efficiencies.

Guidance and Strategy:

The subcommittee recommends that a:

> *"BSE task force, which includes government and non governmental stakeholders, is established under the leadership of the USDA …"*

USDA already satisfies this recommendation as the Department has several existing mechanisms to assure appropriate guidance and involvement from outside experts and interested stakeholders. The interagency Transmissible Spongiform Encephalopathy (TSE) Working Group meets regularly to consider department questions and concerns regarding all of the TSEs, including BSE. Furthermore, the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases (SACFAPD) meets regularly and can also solicit public and expert advice. Indeed, this international review team was convened as a subcommittee of the SACFAPD.

The subcommittee also recommends:

> *"Close collaboration between all appropriate agencies in NAFTA is essential for the proper management of North America's BSE problem."*

USDA has historically and routinely met with our neighbors and trading partners on animal and plant health risk mitigation measures. Indeed, we have a standing North American Animal Health Committee that includes chief veterinary officers from Canada, Mexico, and the United States. This group has developed and is working to implement a North American BSE strategy. After the finding in Canada in May, 2003, U.S, Canadian, and Mexican officials sent a letter to the OIE (the world animal health organization) regarding a scientific approach to BSE and trade issues. The United States has also taken a leadership role by proposing a new "minimal risk" BSE class for countries with historic mitigation measures and a low incidence of BSE, covering identified low risk products.

The USDA will also work with the *Harvard Center for Risk Analysis* for further risk characterizations, and reductions in that risk achieved by the changes USDA has

implemented since December 23, 2003. These further analyses will be conducted in collaboration with members of the subcommittee.

---

[1] Report of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases. "Measures Relating to Bovine Spongiform Encephalopathy in the United States". Available at: http://www.aphis.usda.gov/lpa/issues/bse/bse_sec_adv_comm.doc

[2] Animal and Plant Health Inspection Service (APHIS), Veterinary Services. "Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States". October 2003. Available at: http://www.aphis.usda.gov/lpa/issues/bse/bsecan_risk_anal.pdf

[3] Cohen, Joshua T. and George M. Gray. "Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity in the United States from Canada". Available at: http://www.aphis.usda.gov/lpa/issues/bse/harvard_10-3/text_wrefs.pdf. This document was updated in 2004. See Cohen, Joshua T. et. al. "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States". Available at: http://www.aphis.usda.gov/lpa/issues/bse/madcow.pdf